REQUEST FOR PROFESSIONAL SERVICES

Contracting Officer Technical Representative (COTR): Edward Hudgens, Chemist, EB/EPHD/NHEERL, tel: 919-966-0642, fax: 919-966-0655

SUGGESTED CONTRACTOR:
Rosemarie Bowler, Ph.D.
C/O:
San Francisco State University, Office of Research & Sponsored Programs
1600 Holloway Avenue, ADM 471
San Francisco, CA 94132
Contact: Alison Sanders
Tel: (415) 338-7094
Fax: (415) 338-2493
Email: asanders@sfsu.edu **SFSU's DUNS #**: 942514985

PERIOD OF PERFORMANCE: 33 months from date of issuance, a suggested period of April 15, 2011 - January 14, 2014. Interim payments are allowed based on the following schedule:

1. After EPA acceptance of the Study Plan, QA Plan and Data Analysis Plan, 20%
2. After EPA acceptance of the Interim Report, 40%
3. After EPA acceptance of the Final Report, 30%
4. After Completion and Journal Acceptance of the Final Manuscript, 10%

SOLE SOURCE JUSTIFICATION:

The procurement of the services specified in the attached Request for Professional Services is recommended to be processed without full and open competition. The project "An Epidemiologic Health Study of Manganese Exposure in East Liverpool, Ohio" has been selected by Region 5 to be funded under the Regional Applied Research Effort sponsored by the Office of Science Policy. The proposed contractor, Rosemarie Bowler of San Francisco State University, conducted an epidemiologic health study of manganese exposure in Marietta, OH and Mt. Vernon, OH as part of a previous RARE project. The data from these two towns is proprietary, containing Personally Identifiable Information such as address, which cannot be passed to another organization. The East Liverpool, OH study must use the same protocol, selection criteria and measurement techniques to ensure the study results are comparable across the three towns. Therefore, the proposed contractor is the only one with the capability to conduct the proposed new study using the same protocol, selection criteria and measurement techniques which will ensure that data can be compared across the three communities and enable access to the previous studies' data for spatial analyses. Due to proposed contractor's unique ability, it is recommended that this professional services contract be granted without competition.

AUTHORITY AND FAR REFERENCE

The basis for this recommendation is 41 U.S.C. 253(c)(1); FAR 6.302-1; only one responsible source.

STATEMENT OF WORK

A. Background Information

Potential neurotoxicity from airborne Manganese (Mn) exposure has been a community and risk assessment concern for more than a decade in Region 5 (e.g. OH, MI). The RARE program funded a 2009-2010 Mn health study in Marietta OH near a large industrial emitter of airborne Mn, led by Rosemarie Bowler of San Francisco State University. Mt. Vernon OH, demographically similar to Marietta but without large industrial Mn emission sources, was used as the comparison community for Marietta. Initial Marietta-Mt. Vernon comparisons generally indicate a lack of major health effect differences between the two towns. Whether this extends to East Liverpool OH, an area of much higher (up to 50-fold) outdoor air Mn concentrations is the present research question of interest, and a central reason for extending the Marietta-Mt. Vernon study.

Some of the highest chronic US residential Mn inhalation exposures are likely to have occurred in East Liverpool, OH. The proposed work is important in that either positive results (differences between East Liverpool and comparison communities) or negative results (little or no differences among communities) inform the issue of potential health effects of residential airborne Mn exposure, a recognized gap in Mn health effects literature. Therefore, either outcome can help inform the need for greater airborne Mn control. In addition, the present proposal addresses the USEPA Administrator's environmental justice priority. The poverty rate is higher in East Liverpool (25.2%) than in Marietta (16.9%), Mt. Vernon (15.6%), the State of Ohio (7.8%) or the U.S. (9.2%).

B. Purpose and Objectives

This study will evaluate whether long term (minimum 10 years) residential airborne Mn exposure can affect human health, and will compare already available Marietta and Mt. Vernon adult resident results with those of East Liverpool for biomarkers (blood metals, toenails, hair), medical tests (symptoms; illnesses; Unified Parkinson's Disease Rating Scale evaluation), functional tests (mood; neuropsychological tests such as working memory and attention, verbal skills, motor dexterity/strength, visual tracking speed); and questionnaires (life style habits; work; dietary Mn). Key research questions include:

- Are blood and plasma Mn (controlled for Cd, Hg, and Pb exposure by measuring these metals in whole blood; controlled for Fe status and liver function by measuring plasma ferritin and the hepatic enzymes ALT and GGT, respectively) significantly elevated in East Liverpool adult residents vs. those in Marietta and Mt. Vernon? An additional novel diagnostic biomarker using toenails and hair shall be used to assess longer term Mn exposure (7-10 months).
- What differences in environmental and lifestyle factors may contribute to blood, hair, and toenail Mn levels in East Liverpool residents?
- Is Mn body burden associated with altered neurological and neuropsychological function, or medical symptoms and illnesses?
- Do health outcomes (e.g. neuropsychological test results) differ among the three towns?
- Can Mn exposure-effect relationships with health and illness be shown through use of a

cumulative exposure index?

This study will require the approval of the EPA's Institutional Review Board (IRB) of Record, the University of North Carolina Biomedical IRB, and the EPA's Human Studies Subjects Official before any recruitment activities can commence.

C. Specific Objectives/Milestones to be Performed by the Contractor

The contractor will plan, recruit, conduct, analyze data, produce reports and manuscripts for this study.

Plan: The contractor shall develop the following plans:

1. A Quality Assurance Project Plan for the overall study. The EPA will provide a template within 14 calendar days of award of this contract.

2. A Study Plan that will include recruitment, data collection, sample collection, sample processing, sample storage, sample shipping, toenail Mn sample analysis, hair Mn sample analysis and incentive payment procedures. The EPA will provide a template within 14 calendar days of award of this contract. This plan shall include the qualifications of the individuals performing activities that require specialized training or certifications; such as, but not limited to, phlebotomy and standardized neurological testing. This plan shall use the same type of recruitment sampling strategy that was used in Marietta, OH. Exclusion criteria shall be identical to the Marietta study, which included: having other chemical exposures, having less than ten years of residence in the study area, working at the SH Bell Company (source of Mn emissions) or any industrial company that produces Mn emissions, having had any major illnesses that would affect neurological and/or neuropsychological function, and women pregnant or breastfeeding. To avoid possible groundwater contamination, only those residents on the municipal water supply shall be eligible to participate. As part of this plan, the contractor shall provide materials for Institutional Review Board applications, a copy of the IRB package that they submit to their IRB of record, and a copy of that IRB's approval. The contractor shall identify an appropriate location to conduct the field study in East Liverpool, OH.

3. A data analysis plan that will include air Mn estimation (either monitor, emissions or modeled, using data provided by the EPA) for East Liverpool, OH. The plan shall include data analysis procedures to assess the relationship between Mn exposure and neurologic health outcomes and other health or symptom outcomes, and to compare these neurologic health/other health outcomes for the three Ohio towns (East Liverpool, Marietta, and Mt. Vernon, OH).

Recruit: The contractor shall not recruit or go into the field prior to receiving EPA Human Subjects Research Approval, including Institutional Review Board Approval(s). After the EPA approval of the plans listed above, the contractor shall canvas the study area using the same

type of statistical sampling strategy that was used in the Marietta, OH study to obtain a pool of potential study participants. The contractor shall recruit no more than 120 participants from East Liverpool, OH, between the ages of 30-75 years. The goal for this study is to have 100 individuals successfully complete the study protocol.

Conduct: The contractor shall conduct the study based upon an EPA approved study plan. After obtaining Informed Consent from the participant, the contractor shall attempt to collect the following information or samples: responses to the health questionnaire, whole blood samples, serum samples, toenail samples, hair samples, and results of standardized neurological tests such as UPDRS, CATSYS, Cognitive, Motor and Tremor, and Mood. The contractor shall process, store, and ship all biological samples using procedures in the EPA approved Study Plan. Due to the high visibility of this study, the EPA may require a Technical Systems Review (TSR, QA audit) of this study. The contractor shall be prepared to be QA audited by the EPA. The contractor shall ship the whole blood to the same laboratory used in the Marietta study for the analysis of a metals panel which includes Mn. The contractor shall ship nails and hair samples to the approved location for Mn content analysis. The contractor shall ship the serum samples to an EPA point of contact, to be named after the award of this contract, for subsequent Ferritin and liver enzymes analyses. The contractor shall be responsible for the disposal of all materials used during the sample processing or analysis work. The contractor shall ship any unused sample to the EPA upon completion of the analysis work.

Analyses/Reports/Manuscripts: The contractor shall analyze the data from this study according to the approved data analysis plan. The contractor shall write the following:

1. An Interim Report which describes the conduct of the field collection of information and samples. A draft of this report shall be due within 30 calendar days of the completion of the field study. The EPA will review and provide comment on this report within 15 calendar days. The contractor shall incorporate any EPA comments and provide a final version of this report no more than 15 calendar days after the receipt of the EPA's comments.
2. A Final Report which details the data analysis results and contains all biological sample laboratory analysis results. A draft of this report shall be due within 10 months of the completion of the field study. The EPA will review and provide comment on this report within 21 calendar days. The contractor shall incorporate any EPA comments and provide a final version of this report no more than 30 calendar days after the receipt of the EPA's comments.
3. A journal article suitable for submission to a peer-reviewed journal such as Environmental Health Perspectives or Neurotoxicology. The contractor shall prepare a draft for comment by the EPA within two months of the EPA's acceptance of the Final Report. The EPA will provide comments on the draft within 21 calendar days of receipt. The Contractor shall incorporate any EPA comments, clear the article through the EPA Clearance Process and submit the article to the specified Journal. The Contractor shall be responsible for incorporating reviewer comments and for all publication charges.

D. Government Responsibilities

The government researchers will be responsible for obtaining approval for the study from the EPA IRB of record, the University of North Carolina Institutional Review Board, and EPA Human Subjects Approval. The government researchers will provide templates for QAPP, Study Plan and IRB submission materials within 14 days of award of this contract. The government researchers will provide estimates of air Mn levels in East Liverpool, OH for the study time period. If the EPA requires a Technical Systems Review of this study, the government researchers will provide a copy of the TSR final report. The government researchers will perform the serum Ferritin and liver enzymes analyses and provide the results to the contractor. The government researchers will provide comments on the Interim Report within 15 calendar days of receipt, will provide comments on the Final Report within 21 calendar days of receipt, and will provide comments on the journal article within 21 calendar days of receipt.

E. Contracting Officer's Technical Representative Designation

The Contracting Officer's Technical Representative for this Simplified Acquisition will be:

Edward E. Hudgens

Chemist

US EPA/ORD/NHEERL/EPHD/EB (MD-58C)

Research Triangle Park, NC 27711

Telephone: 919-966-0642

Fax : 919-966-0655

Email: hudgens.edward@epa.gov

The preferred method of contact is by email.